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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/512,829 | 02/25/2000 | David S. Garvey | | 6724 |

25270 7590 02/26/2002

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EXAMINER

RAO, DEEPAK R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1624

DATE MAILED: 02/26/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/512,829

Applicant(s)
Garvey et al.

Examiner
Deepak Rao

Art Unit
1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 13, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-45, 50, 51, 59, 60, 64, 66, 68, 71, 72, and 79-84 ☐ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 36-45, 50, 51, 59, 60, 64, 66, 68, 71, 72, and 79-84 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1624

DETAILED ACTION

This office action is in response to the amendment filed on December 13, 2001.

Claims 36-45, 50-51, 59-60, 64, 66, 68, 71-72 and 78-84 are currently pending in this application.

The scope of the invention has been changed. The claims that were originally presented and examined were drawn to products and corresponding methods of use. The instant claims are drawn to different uses of the products. Upon reconsideration the following restriction requirement is deemed necessary.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 50-51, 64, 36-45 and 79-84, drawn to a method for improving the gastroprotective properties, etc. of a proton pump inhibitor, classified in class/subclass various.
- II. Claims 59-60 (in part), 36-45 and 79-84, drawn to a method for preventing or treating a gastrointestinal disorder with the exception of a *Helicobacter Pylori* associated disease using a proton pump inhibitor, classified in class/subclass various.

Art Unit: 1624

- III. Claims 66, 36-45 and 79-84, drawn to a method for decreasing or reversing gastrointestinal toxicity, etc. by using a proton pump inhibitor, classified in class/subclass various.
- IV. Claims 68, 59-60 (in part), 36-45 and 79-84, drawn to a method for treating an infection caused by *Helicobacter Pylori* or a *Helicobacter Pylori* associated disease using a proton pump inhibitor, classified in class/subclass various.
- V. Claims 71-72, 36-45 and 79-84, drawn to a method for treating a viral infection using a proton pump inhibitor, classified in class/subclass various.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because a method for improving the properties of proton pump inhibitors is independent from a therapeutic method of treating a gastrointestinal disorder. The subcombination has separate utility such as treating a gastrointestinal disorder, etc.

Inventions I-V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each invention has separate utility such as method for

Art Unit: 1624

improving gastroprotective properties or a method for treating a viral infection, etc. all of which are different. See MPEP § 806.05(d).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Claims are generic to a plurality of disclosed patentably distinct species comprising various proton pump inhibitors such as benzimidazole, quinoline, etc. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1624

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Deepak Rao
February 24, 2002